



Virginia  
Regulatory  
Town Hall

[townhall.virginia.gov](http://townhall.virginia.gov)

## Proposed Regulation Agency Background Document

<b>Agency name</b>	Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12 VAC 5 - 490
<b>Regulation title</b>	Radiation Protection Regulations: Fee Schedule
<b>Action title</b>	Amend fee schedule to increase X-ray machine registration and inspection fees
<b>Date this document prepared</b>	December 3, 2007

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

### Brief summary

*In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.*

The Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulations: Fee Schedule (12 VAC 5- 490) to adopt new X-ray machine registration fees, and to include additional types of X-ray machines in the inspection fee schedule. These proposed regulations are intended to supersede the Radiation Protection Regulations: Fee Schedule, which became effective January 1, 1989.

**NOTE: A Notice of Intended Regulatory Action (NOIRA) was published in the Virginia Register on 2/5/2007. That publication provided notice of an intent to propose regulations these regulations, as well as a separate set of amendments that have proceeded separately to a different point in the promulgation process. (This separate set of amendments currently has a Town Hall Action/Stage number of 2191/4281.)**

### Legal basis

*Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.*

---

These regulations are authorized by the Code of Virginia, Sections 32.1-229 et seq. Section 32.1-229.1 requires the Board of Health to establish fee schedules for registration of machines, for inspections of X-ray machines by Department of Health personnel (except for audit inspections initiated by the Department). Section 32.1-229.2 requires the Board of Health to set inspection fees to minimize competition with the private sector and include all reasonable costs.

Refer to the following web sites for viewing these sections of the Code:

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1>

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.2>

## Purpose

*Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.*

---

The proposed regulatory action addresses two sets of fees levied by the X-ray machine program: X-ray machine *registration fees* and X-ray machine *inspection fees*. With respect to the X-ray machine *registration fees*, the existing regulation is being amended due to the increased costs of maintaining a registration program for X-ray machines since publication of the fee schedule with an effective date of January 1, 1989. The *registration fees* need to be adjusted to decrease the growing reliance on general funds to support this activity. The X-ray machine *inspection fees* also need to be modified. There now exist several types of X-ray machines that did not exist in 1989, for which the agency does not have an appropriate *inspection fee*--fees for these machines are now included in the proposed X-ray machine inspection schedule. The personnel and travel cost to the agency for machine inspections have also increased since the fee schedule was established in 1989.

The harmful effects of radiation are well known, as well as the many beneficial applications of radiation in industry and healthcare. Adequate regulatory controls for the useful application of radiation is necessary to protect the health, safety and welfare of citizens. The Commonwealth seeks to fully cover the costs of the X-ray machine program from registration fees by SFY2010.

## Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)*

---

Section 10 of the Regulations is to be amended to increase the X-ray machine *registration fee* of \$15 annually to \$50 for those facilities on an annual inspection frequency; to increase the fee of \$15 to \$50 every three years for those facilities on a three year inspection cycle; and to consider higher registration fees for radiation therapy machines and particle accelerators.

Section 20 of the Regulations is to be amended to revise the X-ray machine *inspection fees* for the various types of X-ray machines based on existing costs to the agency and to develop inspection fees for

bone densitometers; combination dental panoramic and cephalometric machines; and other X-ray machine types which were not included in the fee schedule.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*  
1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*  
2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*  
3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

*If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

---

1. Primary advantages and disadvantages to the public:

The primary advantage to the public is that the X-ray machine registration and inspection activities will rely less on general funds to support these activities and more on the users of the X-ray equipment.

There are no disadvantages to the public in promulgating the proposed fee schedule.

2. Primary advantages and disadvantages to the agency and Commonwealth:

Approving the proposed fee structure will allow the Commonwealth to recover more of the costs associated with carrying out the legislative mandate.

There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule.

3. Other pertinent matters of interest to the regulated community:

X-ray machine registrants have an interest in keeping inspection fees as low as possible.

Private inspectors of X-ray machines have an interest in assuring that inspection fees by agency inspectors do not hurt their business by undercutting the private sector pricing, and the *Code of Virginia* Section 32.1-229.2 requires the agency to establish inspection fees in such a manner so as to minimize competition with the private inspector while recovering costs.

**Requirements more restrictive than federal**

*Please identify and describe any requirement of the proposal which are more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

---

There are no applicable federal requirements or no requirements that exceed applicable federal requirements

**Localities particularly affected**

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

None

**Public participation**

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or less costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Les Foldesi, Director, Division of Radiological Health, VDH 109 Governor Street, Room 732, Richmond, VA 23219, Phone:(804) 864-8151, FAX (804) 864-8155, (e-mail: [Les.Foldesi@vdh.virginia.gov](mailto:Les.Foldesi@vdh.virginia.gov)). Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

**Economic impact**

*Please identify the anticipated economic impact of the proposed regulation.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b></p>	<p>Of the \$892,801 in general funds allocated for service area 56504 in SFY2008, approximately \$400,000 is used to support the X-ray registration and inspection activity. This is partially offset for the Commonwealth by the fees collected. The program generates \$120,000 to \$135,000 from X-ray registration fees annually, which are deposited into the general fund (fund detail 02198). The program generates approximately \$85,000 in annual inspection fees which are deposited into the general fund (fund detail 02689). Staff anticipates the funding source will become special funds 0200 beginning in SFY2009. Program expenditures are primarily on-going expenditures and are expected to increase annually with salary adjustments due to cost of living raises.</p>
---	---

<p><b>Projected cost of the regulation on localities</b></p>	<p>There are no direct charges to the localities, which are exempt from registration fees for X-ray machines. Nevertheless these facilities are required to register their X-ray machines. The indirect cost would include postage and staff time (approximately 15 minutes) to complete the registration form.</p>
<p><b>Description of the individuals, businesses or other entities likely to be affected by the regulation</b></p>	<p>Entities affected by the regulation include: health care facilities ranging from single practitioner to major medical centers; engineering and industrial firms; and security screening.</p>
<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are over 17,000 X-ray machines used in 3,127 dental facilities, 584 chiropractic facilities, 230 podiatry offices, 1,305 medical facilities, 742 veterinary facilities, 215 state facilities, 5 state hospitals, and 99 other hospitals. The following types of facilities are assumed to be small businesses: 3,127 dental facilities, 584 chiropractic facilities, 230 podiatry offices, 1,305 medical facilities, and 742 veterinary facilities</p>
<p><b>All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.</b></p>	<p>X-ray Registration Fees: Direct Costs for implementing this regulation will be \$50 per X-ray tube annually for those facilities on a one year machine inspection cycle (Medical, hospitals, and chiropractic), and every three years for those facilities on a three inspection cycle (dental, podiatry, and veterinary). Indirect cost includes the facility staff time to prepare and submit a registration form (approximately 15 minutes), cost of generating a check to VDH in response to a VDH invoice, and postage (approximately \$20).</p> <p>X-ray Inspection Fees: Direct Costs for implementing this regulation will be dependent on the type of X-ray machine and will range from \$90 for a simple dental intra-oral machine, to \$230 for a moderately complex general purpose machine, to \$460 for a complex fluoroscopic X-ray machine. The direct cost may be an annual expense or incurred every three years depending on the facility’s inspection cycle. X-ray machine facilities may chose to obtain the services of an approved Private Inspector rather than use a VDH inspector. Private inspector fees for services are independently negotiated with each facility, and may be higher or lower than VDH’s proposed inspection fees. Indirect costs for the inspection requirement include staff time to schedule either a Private Inspector or a VDH inspector, to submit an Inspector’s report to VDH, to keep record of inspection reports and correspondences, and, if a VDH inspector is used, to prepare a check in response to a VDH invoice (approximately \$50 per year, including postage).</p>

--	--

**Alternatives**

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

Abolishing the regulation or failure to update the existing regulation would result in an underfunded and ineffective program, putting the public at greater risk of unnecessary and potentially harmful radiation exposure. General fund and federal grant support streams are insufficient to cover to costs of a safety program envisioned and mandated by statute.

**Regulatory flexibility analysis**

*Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

1. Approximately two thirds of the facilities are on a three-year registration and inspection cycle rather than an annual registration and inspection cycle. Those facilities on a three-year cycle represent the majority of small businesses.
2. The establishment of schedules or deadlines for compliance with registration or inspection requirements are consistent with other states. Less stringent inspection requirements may result in undetected non-compliances that may adversely affect patient care and safety. Less stringent registration requirements may adversely impact the reliability and value of the X-ray machine database.
3. The fee schedules were kept as simple as possible.
4. Establishment of performance standards in place of operational standards does not appear to be applicable to implementing a fee schedule.
5. Most of the entities this regulation applies to are small businesses. The Code of Virginia does not provide exemptions for the requirements of this regulation.

**Public comment**

*Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.*

Commenter	Comment	Agency response
Pamela Gebhart-Cline, MSFEd,RT (R) (M)-Riverside School of Health Careers	I do not know what the current fee schedule is nor do I know what the range is proposed however I request that you give special consideration to academic settings. If a school has an energized lab or radioactive substances for educational purposes only (not those shared by institutions that provide patient care and are reimbursed for the same) it is my belief that schools should pay less due to the nature of their business.	Not Applicable. The comment appears to be in the context of the radioactive materials fees published in the NOIRA and addressed in a separate regulatory action.

**Family impact**

*Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

The proposed changes would not have a direct impact on the institution of the family and family stability.

**Detail of changes**

*Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.*

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all changes between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
2VAC5-490-10	N/A	All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following	All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee: \$15 <del>\$50</del> for each machine and additional tube(s) that have a required annual

		<p>registration fee: \$15 for each machine and additional tube(s) that have a required annual inspection, collected annually;</p> <p>\$15 for each machine and additional tube(s) that have a required inspection every three years, collected every three years.</p> <p>All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:</p> <p>\$15 for each machine with a maximum beam energy of less than 1 Mev;</p> <p>\$15 for each machine with a maximum beam energy of 1 Mev or greater.</p> <p>Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.</p>	<p>inspection, collected annually;</p> <p><del>\$15</del> <u>\$50</u> for each machine and additional tube(s) that have a required inspection every three years, collected every three years.</p> <p>All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:</p> <p><del>\$15</del> <u>\$50</u> for each machine with a maximum beam energy of less than <del>1 Mev</del> <u>500 KVp</u>;</p> <p><del>\$15</del> <u>\$50</u> for each machine with a maximum beam energy of <del>1 Mev</del> <u>500 KVp</u> or greater.</p> <p>Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.</p> <p>Rationale: Cost of postage, data processing equipment and personnel</p>
--	--	---	--

<p>12VAC5-490-20</p>		<p>Inspection fees. The following fees shall be charged for surveys requested by the registrant and performed by a Department of Health inspector:</p> <p>Cost Per Type Tube</p>	<p>expenses have increased considerably since the fee schedule was first implemented in 1989. Fees set to generate revenue to support the activity at SFY2008 levels (\$400,000) until the next regulatory review cycle in three years.</p> <p>Inspection fees. The following fees shall be charged for surveys requested by the registrant and performed by a Department of Health inspector:</p> <p>Cost Per Type Tube</p>
		<p>General Radiographic(includes: Chiropractic, Mammographic, Podiatric, Veterinary, Cephalometric, and Special Purpose X-ray Systems) \$190</p> <p>Fluoroscopic, C-arm Fluoroscopic \$190</p> <p>Combination (General Purpose-Fluoroscopic) \$380</p> <p>Dental Intraoral, Cephalometric and Panographic \$ 65</p>	<p>General Radiographic (includes: Chiropractic, <del>Mammographic, Podiatric, Veterinary, Cephalometric,</del> and Special Purpose X-ray Systems) <u>\$230</u></p> <p>Fluoroscopic, C-arm Fluoroscopic <u>\$230</u></p> <p>Combination (General Purpose-Fluoroscopic) <u>\$460</u></p> <p>Dental Intraoral, <del>Cephalometric</del> and Panographic <u>\$ 90</u></p> <p><u>Veterinary</u> <u>\$160</u></p> <p><u>Podiatric</u> <u>\$ 90</u></p> <p><u>Cephalometric</u> <u>\$120</u></p>

		None	<p><u>Bone Densitometry</u> \$ 90</p> <p><u>Combination (Dental Panoramic and Cephalometric)</u> \$210</p> <p><u>Shielding review for dental facilities</u> \$250</p> <p><u>Shielding review for radiographic, chiropractic, veterinary, fluoroscopic, or podiatric facilities</u> \$450</p> <p>Rationale: Personnel and travel expenses have increased since implementation of fee schedule in 1989. VDH has received increasing number of shielding review requests and requires significant staff time.</p>
--	--	------	--